

# **The Dianatal® option: Experiences in the therapeutic approach**

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**Prof. Dr. Maritta Kühnert**

**Dept. of Obstetrics and Perinatology  
Philipps-University Marburg**





DIANATAL® Obstetrik Gel  
Zur Geburtskürzung und Schmerz-  
Für better childbirth and perineal protection  
Pour faciliter la naissance et ainsi protéger le périnée  
Per la facilitazione del parto e la protezione del perineo  
Para la facilitación del parto y la protección del perineo  
Dla ułatwienia porodu oraz ochrony krocza



# Different forces during Childbirth:

## Beneficial during labor:

- labor
- gravity
- Normal pelvic sizes and form

## Inhibitory during labor:

- Elasticity of the cervix
- friction between:  
fetus + birth canal
- borderline pelvic sizes  
or form

# Which Substrates are available?

## Substrate:

- Lubricating jelly
- Olive oil
- Oil for perineal massage

## Attributes + Quality:

- Hygiene? Very fluid
- Hygiene? Fluid
- More friction in combination with amniotic fluid; essential oils can irritate the eyes of the newborn; foreign body reactions may occur

# Which Substrates are available?

## Substrate:

- Dianatal® Obstetric Gel:

## Attributes + Quality :

- Sterile single-use packaged; tested, non-allergenic, latex-free, examined in accordance with international and FDA guidelines concerning its biocompatibility; electroconductive; 2 pharmaceutical forms available: for Stage 1 = mucous; Stage 2 = liquid

## **Preventive use:**

**Starting at the onset of regular contractions  
in primiparous and multiparous women with vaginal  
delivery intend  
(application during labor stage 1 and labor stage 2)**

# **Therapeutic use:** *(application in case of)*

1. **labor arrest**
2. **indication for obstructed or delayed delivery**
3. **preterm delivery**
4. **non-lubricated vagina after several applications of prostaglandin gel in case of induction of labor**
5. **facilitation of vaginal operative procedures**
6. **facilitation of manual placenta delivery**
7. **indication for labor facilitation in case of history with C- section, state after obstructed labor, big baby, borderline pelvic sizes**

## **Marburg Protocol of Application:**

**The patient will be informed to have the possibility to take part in the Dianatal® application study**


**The patient gets a written information concerning the study and has a confidential discussion with midwife or obstetrician**

**In case of to participate in the study the patient has to sign for informed consent:**

***Thereafter the application study could start!***

# Marburg Protocol of Application:

**Dianatal Geburtsgel: Anwendungsbeobachtung**



**1. MUTTER**

Vorname / Name (Initialen)  Alter

GA in Wo + Tg  MM bei Gebseintritt cm

Parität 1.  2.  3.

Geburtseinleitung ja  nein  wenn ja, wie?

Anwendungsart: **Gelgeburt\***  **therapeutisch**  (protrah. Geb-verlauf, Vakuum, ...)

**2. GEBURT**

	Uhrzeit (Std; Min)	Datum (Tg; Mt)
<b>Muttermund bei Geburtsbeginn</b>	<input type="text"/>	<input type="text"/>
<b>Muttermund 4 cm</b>	<input type="text"/>	<input type="text"/>
<b>Muttermund voll eröffnet</b>	<input type="text"/>	
<b>Geburt</b>	<input type="text"/>	<input type="text"/>

Kindliche Lage vHHL  hiHHL  Deflexionslage

Sekundäre Sectio : nein  ja  bei MM cm Indikation:

Vak/Forz.extraktion : nein  ja  bei MM cm Indikation:

Wassergeburt : nein  ja

**Dammbeurteilung**

Dammintakt  Episiotomie: nein  ja

Dammriss G1  G2  G3  G4

Vaginalriss relevant ? nein  ja  , wenn ja bitte spezifizieren

Plazentarperiode : unauffällig  Komplikationen ja

ACCESS  
Marburg 2005/06

2008, Vers. 1.4

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# Marburg Protocol of Application:

(z.B. atonische Blutung)  
Wenn ja, bitte spezifizieren:

**3. KIND**

m  w  Geburtsgewicht g  KU cm

APGAR – Score 1 Min.  5 Min.  10 Min.

NSA-pH  NSV-pH

Neugeborenenstatus: unauffällig  auffällig  (bitte spezifizieren):

**4. Dianatal EFFEKT**

Wie viel Geburtsgel haben Sie angewendet(ml): 0 bis 10  10 bis 20  20 bis 30

Wie beurteilen Sie den Geburtsverlauf ? (1 bis 5 (schlecht))

Wie beurteilen Sie den Dianatal Effekt ? (1 bis 5 (schlecht))


Geburtsergebnis der Patient:in: (1 bis 5 (schlecht))  
(Bsp. Vaginales Wundgefühl)

Haben Sie Anregungen ?

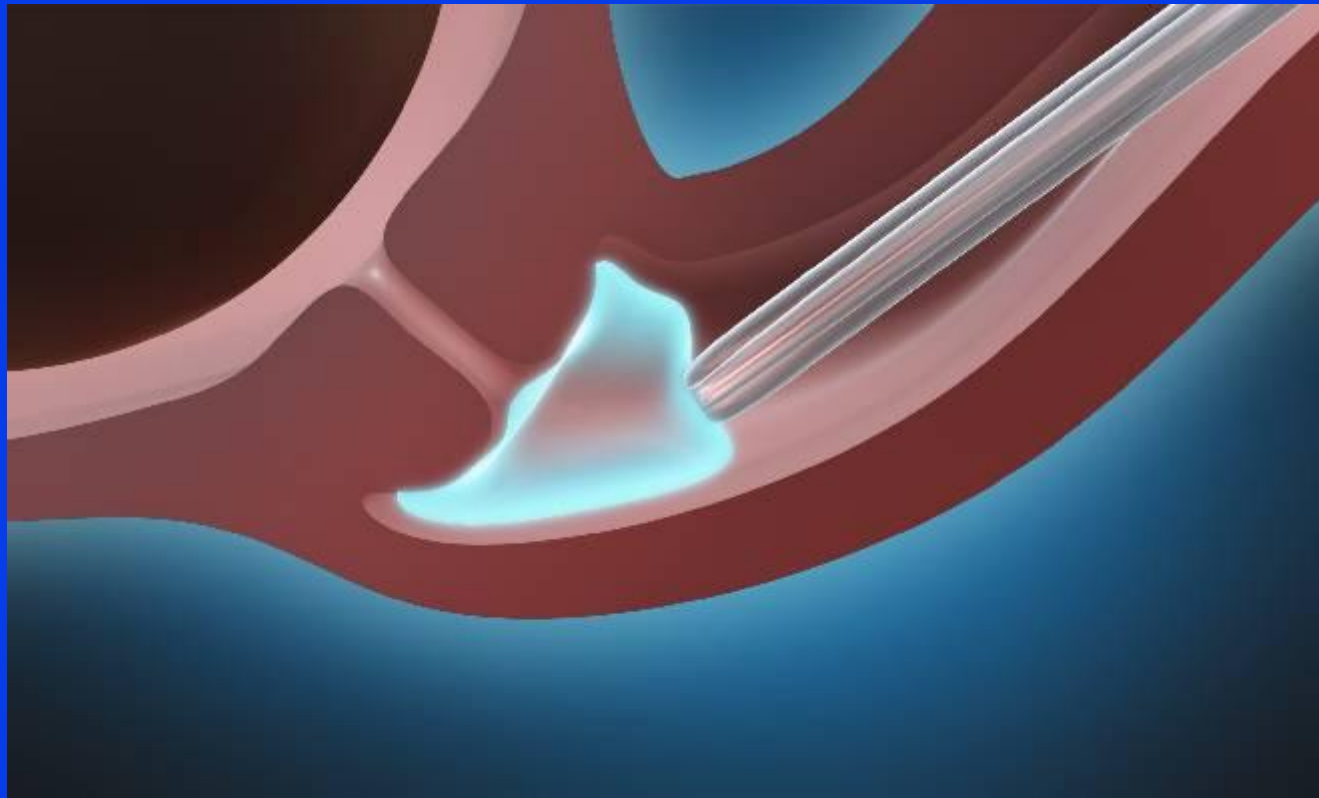
Ort und Datum

Hebamme \_\_\_\_\_ Arzt/-in \_\_\_\_\_

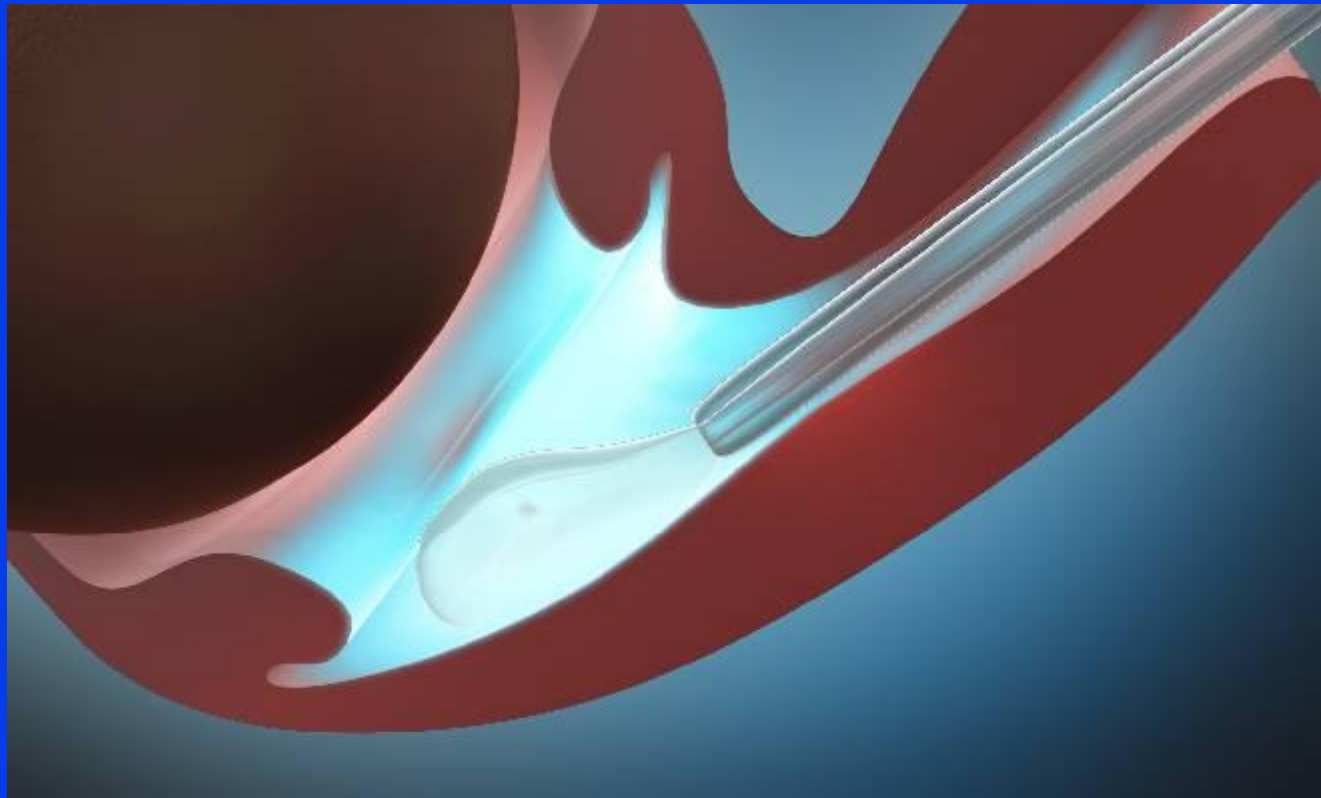
Def: \*Gelgeburt: Anwendung von Dianatal beginnend mit der ersten vaginalen Untersuchung (präventiv)

 II

2008, Vers. 1.6







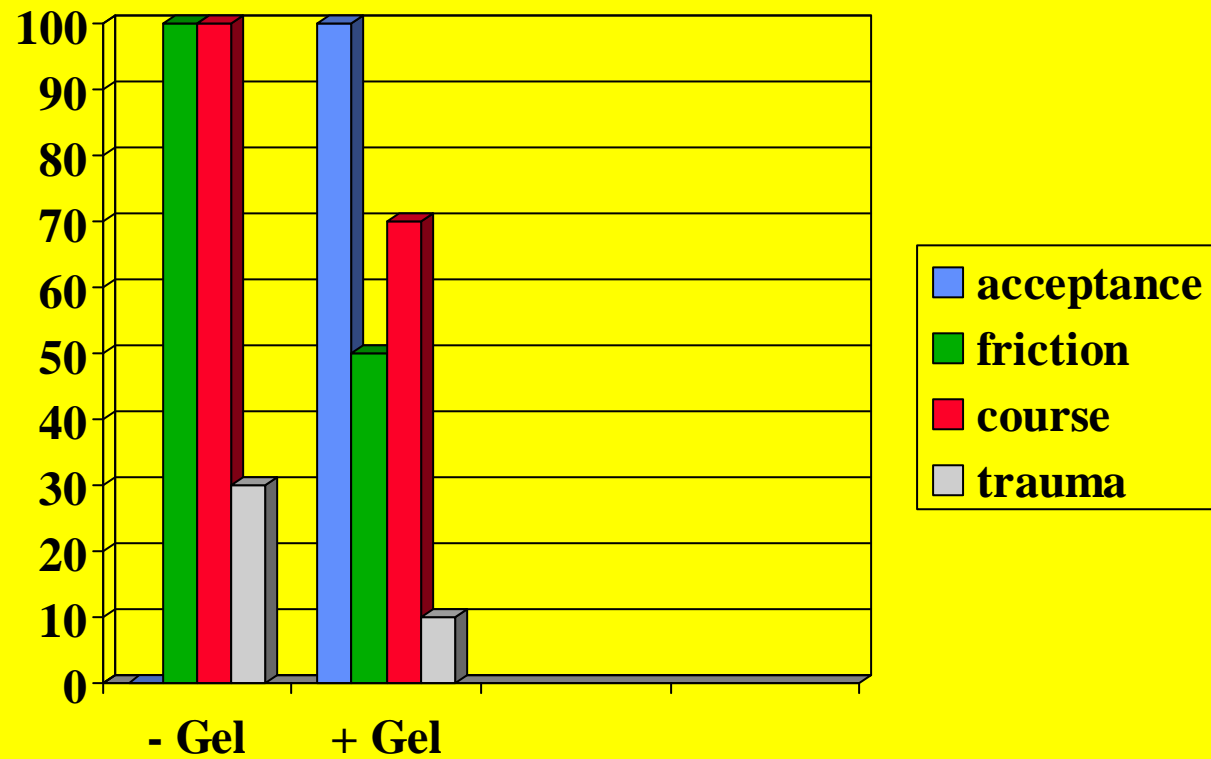




## Scientific principal results by using Dianatal® Obstetric Gel up to now?

- Reduces adhesive and gliding friction significantly by 50 %
- Reduces labor stage 2 significantly by 30 %
- Reduces perineal tears ( pelvic floor + perineum risk, e.g.: birthcanal injuries, incontinence, sexual dysfunction )
- Up to now no known side-effects
- *Influence on the number of C-sections and vaginal-operative deliveries (forceps + vacuum): randomized studies are planned („Works in progress“) concerning scientific output*

## Marburg Experiences (n= 60) :



## Marburg Experiences in the field of therapeutic use :

labor arrest:	0
indication for obstructed or delayed delivery:	17
preterm delivery:	2
non-lubricated vagina after several applications of prostaglandin gel in case of induction of labor:	11
facilitation of vaginal operative procedures:	3
facilitation of manual placenta delivery:	0
indication for labor facilitation in case of history with:	
C-section:	9
state after obstructed labor:	0
big baby:	8
borderline pelvic sizes:	10

## Marburg Experiences up to now :

### Impressions:

- The defined goals can be realized
- Loss of friction
- Reduces labor stage 2 significantly
- Reduces perineal tears

### Reduction of vaginal-operative deliveries

and C-sections should be proved by means of a randomized prospective (Multicenter-) Study, in order to get exact scientific results !

## Costs versus Benefit – Analysis:

- Prevention of C-Sections:  
Difference of costs (DRG´s) vaginal delivery versus C-section = 1280 €!
- Dianatal® Obstetric Gel:  
= 125 € per patient  
If a C-section could be avoided by using Dianatal® :  
reduction of an increased morbidity + mortality for mother + child concerning the following pregnancies (abruptio placenta, placenta praevia, uterine rupture etc.) = reduction of follow-up costs!

## Costs – Benefit – Analysis:

- Lubricant, olive oil, oil for perineal massage:  
Price = 5-10 €
- Dianatal® Obstetric Gel:  
Price= 125 € per patient with 3x11 ml (BRD), up to now not paid by public health service (Gel must be paid privately!)

# Summary:

Last but not least

*„ Who greases well, drives well !“*

that is to say:

1. If there is enough oil in a motor, the motor runs frictionless or smooth

and / or:

2. If you pay good for Dianatal®, you will get a good output, that is to say, probably a smaller amount of operative deliveries with high (follow-up)costs (*a tip for the health insurances*).
3. *Dianatal is a tool to support the salutogenesis of pregnant women (intention to have vaginal child birth)*